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33pp No. 06-1498

IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC
AND PFIZER INC.,
Petitioners,

v.

KIMBERLY KENT, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

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BRIEF OF THE NATIONAL CONFERENCE OF STATE LEGISLATURES, COUNCIL OF STATE GOVERNMENTS, NATIONAL ASSOCIATION OF COUNTIES, AND INTERNATIONAL CITY/COUNTY MANAGEMENT ASSOCIATION AS *AMICI CURIAE* SUPPORTING RESPONDENTS

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QUESTION PRESENTED

Whether federal regulation of drugs impliedly preempts application of the exception to a drug manufacturer's regulatory-compliance defense set forth in Mich. Comp. Laws § 600.2946(5), while leaving the defense itself intact.

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INTEREST OF THE *AMICI CURIAE*

Amici are organizations whose members include state, county, and municipal governments and officials throughout the United States.[1] *Amici* have a strong interest in this Court's preemption jurisprudence and in preserving state-law remedies that effectuate the States' historic responsibility to protect public health and safety. They thus share with the FDA a "core public health mission," U.S. Br. 24, which includes "protecting the public health by ensuring that . . . drugs are safe and effective." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133-34 (2000).

The FDA disclaims any interest in policing fraud by drug companies. *See* U.S. Br. 24. *Amici*, by contrast, have a compelling interest in ensuring that persons like respondents have remedies for intentional torts resulting in injury and death, such as those allegedly committed by petitioners. *Amici* accordingly submits this brief to assist the Court in the resolution of this case.

SUMMARY OF ARGUMENT

1. Petitioners' attempt to expand the reach of *Buckman* to forbid any determination by a state court that could be construed as a finding that fraud was committed on the FDA should be rejected. Evidence that a manufacturer marketed a drug that it knew to be unreasonably toxic prior to seeking FDA

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[1] The parties have consented to the filing of this *amicus* brief and their consent letters have been filed with the Clerk. This brief was not authored in whole or in part by counsel for a party, and no person or entity, other than *amici* and their members, has made a monetary contribution to the preparation or submission of this brief.

approval may well be evidence of "fraud on the FDA," but such evidence has unquestionably been admissible for decades in state products liability litigation. Acceptance of petitioners' argument would make FDA drug approval an absolute immunity to suit and would render remediless the victims of the worst class of tortfeasors—those that intentionally withhold evidence of a drug's toxicity in order to obtain FDA approval. Because Congress did not intend such a result, but rather recognizes that the FDA and the States share a "core public health mission," U.S. Br. 24, petitioners' preemption arguments should be rejected.

Affirmance of the judgment below is also supported by the strong presumption against preemption of state health laws. Such a presumption is particularly strong in this case, where preemption would eliminate respondents' only remedy for petitioners' alleged malfeasance. "It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

Because Michigan's statute is a classic exercise of state police power to protect public health, this case is not controlled by *Buckman*, which involved no exercise of state police power. Under this Court's precedents, the presumption against preemption has special force when the States and the Federal Government are pursuing common purposes.

Affirmance of the judgment below is also consistent with the common law tradition embodied in the Restatement (Third) of Torts: Product Liability (1998). The Restatement confirms that in the overwhelming majority of jurisdictions, compliance with product safety regulation is relevant to the question

of negligence. The Restatement goes much further, however. "When the deliberative process that led to the safety standard with which the defendant's product complies was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency" in question, "compliance with regulation is entitled to little or no weight." *Id.* § 4 cmt. e.

As the Restatement reflects, state courts adjudicating the liability of drug manufacturers have long admitted as proof of negligence evidence that the manufacturers have withheld material information from the FDA. Michigan, by incorporating regulatory noncompliance into its statutory scheme, is simply mirroring what many other state legislatures and courts have been doing for decades. In those States, as in Michigan, evidence of regulatory noncompliance is central to proof of a drug manufacturer's negligence.

2. While the FDA has mechanisms to police fraud, it apparently does not do so to protect the interests of the victims of fraud and did not do so here. Indeed, the FDA has made plain to this Court that when the FDA suspects "fraud on the FDA" it often "reaches a settlement with the applicant in which the applicant pays a fine or takes corrective action (such as changes in labeling) without admitting liability." U.S. Br. 24. The FDA also acknowledges that persons injured by toxic drugs have no private right of action under the FDCA. *Id.* at 4. Given the shared public health mission of FDA and the States, Congress did not intend to preempt traditional state-law remedies such as those asserted here.

Moreover, victims of "fraud on the FDA" are a congressional concern, and Congress has given the States the responsibility to act on that concern. The

FDA argues for a result that would use preemption principles to leave victims of the worst tortfeasors without any legal remedy. That outcome is contrary to Congress's consistent approach of allowing state tort remedies for persons harmed by medication known by the manufacturer to be toxic. The FDA may have discretion to barter away its interest in pursuing fraud against itself, but it cannot, consistent with Congress's intent, barter away the state-law remedies of the victims of such fraud. The judgment below should accordingly be affirmed.

ARGUMENT

Petitioners seek to expand the reach of *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), to forbid any determination by a state court that could also be construed as a finding that fraud was committed against the FDA. The implications of this argument are deeply disturbing because conduct that is evidence of products liability and "fraud on the FDA" has been relevant and admissible in tort litigation for decades.

If this Court accepts petitioners' argument, it will eliminate the only remedy available to victims of the worst class of tortfeasors—those that intentionally withhold from the FDA data on toxic side effects in order to obtain the agency's unwitting approval to market lethal drugs. If the allegations against Warner-Lambert are true, its marketing of Rezulin without full disclosure of its pre-application knowledge about the drug's liver toxicity is a textbook example of such gross malfeasance. *See* Resp. Br. 4–5. Petitioners nevertheless insist that Congress intended to immunize these tortfeasors where state liability is conditioned upon a state court finding that a manufacturer withheld material information from the

FDA, an inquiry that the FDA perceives to be within its exclusive federal province to consider.[2] It is clear that Congress did not intend to create the regulatory void that would result if petitioners prevail.

Amici fully agree with respondents' arguments for affirmance of the judgment below. This brief advances two related arguments: (1) the importance of the presumption against preemption of state health laws to this case, and (2) why a state court's evidentiary finding that a manufacturer withheld material information from the FDA is congruent with Congress's intent to preserve state tort remedies for harms caused by defective and dangerous drugs.

I. THE STRONG PRESUMPTION AGAINST PREEMPTION OF STATE HEALTH AND SAFETY LAWS SUPPORTS AFFIRMANCE.

States are "vested with the responsibility of protecting the health, safety, and welfare of [their] citizens," and have "great latitude" when carrying out that responsibility. *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 127 S. Ct. 1786, 1795–96 (2007). Accordingly, the Court has "long presumed that Congress does not cavalierly pre-empt state law causes of action," particularly in

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[2] The United States contends that "federal law precludes a state rule—whether as an element of a claim or of a defense—that turns on whether FDA would have denied approval or withdrawn it sooner if it had received accurate information." U.S. Br. 21. It also claims that "fraud on the FDA" cannot be a predicate for liability, noting the substantial overlap between the common-law duty relevant to the state proceeding and conduct characterized as "fraud on the FDA." *See* U.S. Br. 27–28 & n.8, 30. Although the Court need not address the issue as broadly as the United States suggests, the Court's opinion could well have ramifications for products liability litigation throughout the country.

"field[s] which the States have traditionally occupied." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). The "presumption against the pre-emption of state police power regulations" is "consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Id.* (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992)).

The presumption against preemption reflects this Court's longstanding reluctance to interfere with the regulatory authority of the States in the absence of Congress's clear intent. *See Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985) ("Where . . . the field that Congress is said to have pre-empted has been traditionally occupied by the States we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977))). The force of this principle is manifest here, where preemption will eliminate the only legal remedy for victims of intentional malfeasance. *See Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) ("It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.").

Because Michigan's statute is a classic exercise of state police power, the outcome in this case is not controlled by *Buckman*, which implicated no such exercise. *See* 531 U.S. at 348 (observing that no presumption against preemption applied to a stand-alone fraud-on-the-FDA claim, "in contrast to situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health

and safety'" (quoting *Medtronic*, 518 U.S. at 485) (internal citation omitted)).

Thus, unlike the claim in *Buckman*, the Michigan statute is subject to a deferential analysis that presumes that Congress expected some degree of overlap between state and federal laws that share the common goal of protecting public health. *See* U.S. Br. 24; *cf. Silkwood*, 464 U.S. at 256 (recognizing the inherent overlap between federal safety regulation under the Atomic Energy Act and state tort law, but holding that "Congress intended to stand by both concepts and to tolerate whatever tension there was between them").

Indeed, this commonality militates towards a particularly robust presumption against preemption. Michigan, no less than the United States, has an interest in the goal of "ensur[ing] that any product regulated by the FDA is 'safe' and 'effective' for its intended use." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (quoting 21 U.S.C. § 393(b)(2)). Under these circumstances, "[t]he presumption against federal pre-emption of a state statute designed to foster public health . . . has special force when it appears . . . that the two governments are pursuing 'common purposes.'" *Pharmaceutical Res. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 666 (2003) (opinion of Stevens, J.) (quoting *New York State Dept. of Social Servs. v. Dublino*, 413 U.S. 405, 421 (1973)).

A. Michigan's Statute Is an Exercise of Police Power to Protect Public Health and Safety, Not an Attempt to Regulate a "Strictly Federal Matter."

Michigan law provides the strongest state-law immunity for drug manufacturers in the nation—an

"absolute defense to a products liability claim if the drug and its labeling were in compliance with the FDA's approval." *Taylor v. SmithKline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003) (construing Mich. Comp. Laws § 600.2946(5)). Drug manufacturers are subject to suit in Michigan only if FDA approval was based on inaccurate or incomplete information or bribery, such that if the truth was known the FDA would not have approved the product or would have removed it from the market. Mich. Comp. Laws § 600.2946(5)(a)–(b).

Michigan enacted section 600.2946(5) because it "was concerned that unlimited liability for drug manufacturers would threaten the financial viability of many enterprises and could add substantially to the cost and unavailability of many drugs." *Rowe v. Hoffman-La Roche, Inc.*, 917 A.2d 767, 775 (N.J. 2007) (quoting *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 967 (6th Cir. 2004)).[3] According to Michigan's Senate Fiscal Agency, "the legislation was based [on] the perception of an 'explosion' in product liability litigation." Resp. Br. 29 n.8 (quoting Michigan Senate Fiscal Agency, SFA Bill Analysis, Revised Enrolled Analysis, S.B. 344, H.B. 4508, at *1 (Jan. 11, 1996)). Such added costs for drug manufac-

[3] In this respect Michigan acted for the same reasons that the United States now represents to be the dual goals of the FDCA: "striking a balance between keeping unsafe products off the market and making efficacious products available to patients and doctors." U.S. Br. 17 n.3. *But see Brown & Williamson*, 529 U.S. at 133-34 (FDA's mission includes "protect[ing] the public health by ensuring that . . . drugs are safe and effective" (quoting 21 U.S.C. § 393(b)(2)); *see also id.* at 162 (Breyer, J., dissenting) ("[T]he [FDCA]'s basic purpose [is] the protection of public health.").

turers could have a direct effect on public health and safety.[4]

At the same time, the Michigan legislature recognized that there are instances in which a drug manufacturer's conduct negates the probative value of FDA approval. This recognition accords with a long tradition in state products liability law that is embodied in the Restatement (Third) of Torts: Products Liability (1998):

> § 4. Noncompliance and Compliance with Product Safety Statutes or Regulations
>
> In connection with liability for defective design or inadequate instructions or warnings:
>
> (a) a product's noncompliance with an applicable product safety statute or administrative regulation renders the product defective with respect to the risks sought to be reduced by the statute or regulation; and
>
> (b) a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.

Id. § 4; *see also* Restatement (Second) of Torts § 288B(1) (1965) ("The unexcused violation of the legis-

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[4] *See Rowe*, 917 A.2d at 774 (sponsors in the Michigan Senate recognized that "[c]onsumers . . . suffer when they are denied new products that would increase public safety or improve their quality of life. . . . [P]roduct liability litigation . . . has added substantially to the cost and unavailability of many goods and services." (quoting Mich. Sen. Fiscal Agency, *supra*, at *10)).

lative enactment or an administrative regulation which is adopted by the court as defining the standard of conduct of a reasonable man, is negligence in itself.").

The Restatement confirms that "[t]he overwhelming majority of jurisdictions hold that compliance with product safety regulation is relevant and admissible on the question of defectiveness, but is not necessarily controlling." Restatement (Third) of Torts: Prod. Liab. § 4 cmt. d Reporter's Note (1998). But "when the deliberative process that led to the safety standard with which the defendant's product complies was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency that promulgated the standard or certified or approved the product," the Restatement emphasizes that "compliance with regulation is entitled to little or no weight." *Id.* cmt. e. Regarding the liability of drug manufacturers for defective prescription drugs, the Restatement expressly provides that "[a] manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to persons caused by the defect." *Id.* § 6.

In essence, section 4 states that regulatory noncompliance, such as "the withholding of necessary and valid information from the agency that . . . approved the product," renders a drug defective, and section 6 makes the manufacturer of that drug liable to persons injured because of its regulatory noncompliance. Thus, state-law principles of regulatory noncompliance complement the federal mission by advancing the common governmental goal of protecting public health. *Compare* Restatement (Third) of Torts: Prod. Liab. § 6(b)(3) (a prescription drug is de-

fective if it "is not reasonably safe due to inadequate instructions or warnings") *with* 21 C.F.R. § 314.2 (2007) (the purpose of the FDA approval process is to "ensure the disapproval of drugs not shown to be safe and effective").

As the Restatement further confirms, state courts have long admitted evidence that drug manufacturers have withheld material information from the FDA as proof of negligence or negligence per se, inadequate warning, or to rebut a defendant's claim of regulatory-compliance immunity. *See, e.g.*, *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1179–80 (5th Cir. 1988) (holding that preemption applies if manufacturer marketed product in compliance with FDA reporting and warning requirements but remanding for inquiry as to "whether and what information the manufacturer withheld from the FDA, if any, and whether possession of this information would have materially altered the contents of the FDA's warning"); *Stanton v. Astra Pharm. Prods., Inc.*, 718 F.2d 553, 563–64 (3d Cir. 1983) (holding that a drug manufacturer's withholding of material information from the FDA was negligence per se under Pennsylvania law); *Toole v. Richardson-Merrell, Inc.*, 60 Cal. Rptr. 398, 409 (Cal. Ct. App. 1967) (holding that "violation of the labeling and marketing provisions of the [FDCA] may be shown to establish negligence").[5] Such a "long his-

[5] *See also In re Medtronic, Inc., Implantable Defibrillators Litigation*, 465 F. Supp. 2d 886, 896 (D. Minn. 2006) (holding that, because plaintiffs' claims that defendant withheld critical information from the FDA were "premised on violations of FDA requirements," those claims were not preempted); *Brown v. DePuy Spine, Inc.*, 22 Mass. L. Rptr. 425 (Mass. Super. 2007) (holding evidence of defendant's failure to disclose known risks to the FDA admissible for the purpose of supporting plaintiff's state law claim of negligence); *Mears v. Marshall*, 944 P.2d 984,

tory of tort litigation" in this area "adds force to the basic presumption against pre-emption." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449–50 (2005).

By incorporating regulatory noncompliance into the statutory scheme, Michigan effectuates the States' historic power to protect public health and safety. Because the purpose of the FDA's regulatory scheme is to "[f]acilitate the approval of drugs shown to be safe and effective" and to "ensure the disapproval of drugs not shown to be safe and effective," *see* 21 C.F.R. § 314.2, it stands to reason that noncompliance with those regulations is evidence that a drug is not safe. Therefore, Michigan's incorporation of regulatory noncompliance into its statute furthers the purpose of ensuring that prescription drugs are safe for its citizens' consumption.

Michigan is far from alone in employing the regulatory compliance doctrine as a source of evidence of negligence in products liability actions. Under Texas law, FDA approval of a drug creates "a rebuttable presumption" of non-liability, which the plaintiff can refute by showing that the defendant "withheld from or misrepresented . . . required information that was material and relevant to the performance of the product and was causally related to the claimant's injury." Tex. Civ. Prac. & Rem. Code

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992 (Or. App. 1997) (holding that claims that defendant "withheld crucial information from the FDA during the initial PMA process" were admissible to support plaintiff's claims of negligence and strict liability); *Green v. Dolsky*, 685 A.2d 110, 117–18 (Pa. 1996) (holding, post-*Lohr*, that the MDA did not preempt claims that "mirror FDA requirements," including claims that defendant "provid[ed] FDA with false, fraudulent, incomplete testing results" and "false, fraudulent, incomplete adverse reaction of injury information").

Ann. § 82.007(b)(1).[6] Statutes in six States use the regulatory compliance doctrine to determine the availability of punitive damages, making evidence of noncompliance admissible to support punitive damages claims that would otherwise be barred by FDA approval.[7]

Six other States have enacted general products liability statutes that create a presumption that a product was not defective, or that a manufacturer was not negligent, if the manufacturer complied with all applicable federal regulations. *See* Ark. Code Ann. § 16-116-105(a); Colo. Rev. Stat. § 13-21-403(1)(b); Ind. Code § 34-20-5-1; Kan. Stat. Ann. § 60-3304(a); N.D. Cent. Code § 28-01.3-09; Tenn. Code

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[6] In 2007, a single-judge trial court ruled that this statute is preempted by the FDA under *Buckman*. *See Ledbetter v. Merck & Co.*, Nos. 2005-59499, 2005-58543, 2007 WL 1181991 (Tex. Dist. Ct. Apr. 19, 2007).

[7] *See* Ariz. Rev. Stat. § 12-701(B) (punitive damages available if defendant withheld or misrepresented "information known to be material and relevant to the harm which the plaintiff allegedly suffered"); N.J. Stat. Ann. § 2A:58C-5(c) (punitive damages available for withholding or misrepresentation of "information which was material and relevant to the harm in question"); N.D. Cent. Code § 32-03.2-11.7 (same); Ohio Rev. Code Ann. § 2307.80(C)(2) (punitive damages available for withholding "information known to be material and relevant to the harm that the claimant allegedly suffered"); Or. Rev. Stat. § 30.927(2) (same); Utah Code Ann. § 78-18-2(2) (same).

While the wording of Michigan's statute is unusual when compared to those quoted above, *see* Mich. Comp. Laws § 600.2946(5)(a) ("the drug would not have been approved or the [FDA] would have withdrawn approval for the drug"), it is clear that this difference is purely semantic and that the Michigan statute is directed at drug manufacturers that withhold or misrepresent evidence which is material to the plaintiff's tort claim. *Cf.* Tex. Civ. Prac. & Rem. Code Ann. § 82.007(b)(1).

Ann. § 29-28-104. Statutes in two States provide that noncompliance with a relevant federal regulation creates a presumption that the product was defective or negligently manufactured. *See* Colo. Rev. Stat. § 13-21-403(2); Kan. Stat. Ann. § 60-3304(b).

The common law of numerous states relies upon the regulatory compliance doctrine as proof of negligence or negligence per se, inadequate warning, or to rebut a drug manufacturer's assertion of regulatory-compliance immunity. *See* discussion at 11–12 & n.5, *supra*.[8] Michigan's statute differs from these laws by granting manufacturers of FDA-approved drugs a *greater* measure of protection from liability: FDA approval creates an immunity from suit, save for the two enumerated exceptions, rather than a presumption that an approved drug is safe. *See Rowe*, 917 A.2d at 772 (presumption created by the Michigan statute is "conclusive," while that created

[8] Violation of any FDCA requirement has long been admissible evidence in state tort suits. *See, e.g., Ezagui v. Dow Chem. Corp.*, 598 F.2d 727, 733 (2d Cir. 1979) (failure to provide adequate warnings of known risks, in violation of the FDCA, was negligence per se under New York law); *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455, 460–61 (4th Cir. 1960) (misbranding in violation of the FDCA was negligence per se under Virginia law); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 964 (E.D. Wis. 1981), *amended by* 532 F. Supp. 211 (E.D. Wis. 1981) (because the FDCA "is designed to protect a class of persons from a particular type of harm, a violation of the statute which results in that type of harm to someone in the protected class constitutes negligence per se" under Wisconsin law); *Batteast v. Wyeth Labs., Inc.*, 560 N.E.2d 315, 323 (Ill. 1990) (violation of FDA regulation may be considered prima facie evidence of negligence if plaintiff belongs to the class the regulation was meant to protect if injury had direct and proximate relation to the regulation); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 71 (Mass. 1985) ("[V]iolation of FDA requirements is evidence, but not conclusive evidence, of negligence.").

by comparable New Jersey statute is merely "rebuttable").

In these States, as in Michigan, evidence of regulatory noncompliance is central to proof of a drug manufacturer's negligence. Whatever other uses this evidence may have under federal law, a court adjudicating a state-law claim may consider whether evidence of a drug's toxicity was withheld from the FDA by the manufacturer for its own purposes. These state laws, like Michigan's statute, are founded on principles of fundamental fairness and the historic responsibility of the States to provide appropriate remedies for intentional torts.

B. Petitioners' Arguments Against Applying the Presumption Against Preemption Are Unpersuasive.

Amici agree with respondents' argument that *Buckman* does not control in this case. Resp. Br. 21–23. The fundamental difference between *Buckman* and this case is that the claim in *Buckman* had no basis in traditional state tort law, because it was asserted against a consulting firm that owed no duty to the plaintiffs. *See* 531 U.S. at 352–53. The Court held that, unlike preemption cases implicating "federalism concerns and the historic primacy of state regulation of matters of health and safety," in *Buckman* "the fraud claims exist solely by virtue of the FDCA disclosure requirements." *Id.* at 348, 352 (quoting *Medtronic*, 518 U.S. at 485).[9] Respondents' claim is entirely different from the plaintiffs' claim in *Buckman* because it arises from the traditional state-

[9] The United States takes the position that "[t]here is . . . no private right of action to enforce the FDCA." U.S. Br. 4 (citing *Buckman*, 531 U.S. at 349 n.4, 352).

law tort duties owed directly to them by petitioners, independent of the FDCA's disclosure requirements.

1. *Non-Compliance with FDA Reporting Requirements Is Not a Unique or Inherently Federal Question That Forecloses Application of the Presumption Against Preemption.*

Petitioners and the United States argue that, rather than being an integral part of traditional state tort law regarding health and safety, a traditional state-law tort claim that implicates fraud on the FDA is "inherently federal in character" and therefore not entitled to the presumption against preemption even when, as here, the provision is part of a state health statute. Pet. Br. 40 (the fact-finder would have to determine whether a defendant "violated *federal law*"); U.S. Br. 14 (presumption does not apply "where the interests at stake are 'uniquely federal' in nature" (quoting *Buckman*, 531 U.S. at 347)). For support, the United States cites *Boyle v. United Techs. Corp.*, 487 U.S. 500, 504–05, 508 (1988), in which this Court held that interpretation of a federal contract was an area of "unique federal concern [that] changes what would otherwise be a conflict that cannot produce pre-emption into one that can." *See* U.S. Br. 14–15.

Petitioners and the United States thus substantially overstate the reach of what is, in fact, a very limited rule. The existence of federal law on a particular subject does not automatically make that subject "inherently federal" in such a way as to eliminate the presumption against preemption. As this Court has stated, "[u]ndoubtedly, every subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, how-

ever, that every federal statute ousts all related state law. . . . Instead, we must look for special features warranting pre-emption." *Hillsborough*, 471 U.S. at 719 (declining to find preemption of local ordinance despite existence of a "federal interest" because "the regulation of health and safety matters is primarily, and historically, a matter of local concern").

Whether Warner-Lambert withheld from the FDA information that Rezulin caused liver damage is neither inherently nor uniquely a matter of federal concern. Rather, the issue is relevant both to federal regulation *and* state tort liability because the facts that establish state tort liability may also be characterized as "fraud on the FDA." In these circumstances, no uniquely federal question is posed, and petitioners must overcome the presumption that Congress intended to coexist state and local regulation of health and safety with federal regulation.

2. ***The Presumption Against Preemption Applies in Conflict Preemption Cases.***

The U.S. Chamber of Commerce contends in its *amicus* brief that "no presumption against preemption applies to the judicial determination of whether preemption is necessary because of an 'actual conflict' between state law and valid federal law." C.C. Br. 8. This is simply incorrect. The presumption against preemption has repeatedly been applied by this Court when considering whether actual conflict exists. *See Cipollone*, 505 U.S. at 518 (holding a state tort action not preempted because of "the presumption against pre-emption of state police power regulations" and because "there is no general, inherent conflict between federal pre-emption of state warning requirements and the continued vitality of

state common-law damages actions"); *Hillsborough*, 471 U.S. at 716 ("Appellee must thus present a showing of implicit pre-emption of the whole field, *or of a conflict between a particular local provision and the federal scheme*, that is strong enough to overcome the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation.") (emphasis added). Furthermore, principles of field and conflict preemption are not "rigidly distinct." *English v. Gen. Electric Co.*, 496 U.S. 72, 79 n.5 (1990). "Indeed, field pre-emption may be understood as a species of conflict pre-emption." *Id.*

Whether or not the term "presumption" is used, this Court has long utilized a practice of examining both the level of state interest and the strength of the perceived conflict when deciding preemption questions. *See American Ins. Ass'n v. Garamendi*, 539 U.S. 396, 420 (2003) ("And since on [Justice Harlan's] view it is legislation within 'areas of . . . traditional competence' that gives a State any claim to prevail, it would be reasonable to consider the strength of the state interest, judged by standards of traditional practice, when deciding how serious a conflict must be shown before declaring the state law preempted." (citation omitted)); *cf. Southern Pac. Co. v. Arizona ex rel. Sullivan*, 325 U.S. 761, 768–69 (1945) (holding, in the Negative Commerce Clause context, that "reconciliation of the conflicting claims of state and national power is to be attained only by some appraisal and accommodation of the competing demands of the state and national interests involved.").

Thus, the exercise of traditional state police powers here—the fundamental difference between the claims in this case and those in *Buckman*—militates

against a finding of preemption, and it is largely a semantic difference whether that analysis is termed a "presumption against preemption," or whether the exercise of state power increases "the strength of the state interest" in balancing state and federal interests to determine whether a conflict exists. Either way, because Michigan has an undeniably strong interest in protecting the health of its citizens, respondents' claims are not preempted under *Buckman*.

II. CONGRESS INTENDED STATE PRODUCT LIABILITY REMEDIES TO COEXIST WITH FDA REGULATION.

The FDCA does not confer upon the FDA the exclusive power to regulate conduct that constitutes fraud and, absent a clear expression of such intent, this Court will not imply it. Moreover, as the FDA concedes that whatever it may be *authorized* to do, it uses the powers vested in it to police fraud to suit its own regulatory purposes and not to protect fraud victims. Consequently, if the Court preempts, it will create an extremely harmful regulatory void that Congress did not intend and leave persons injured by the intentional torts of drug manufacturers without any legal remedy.

A. Congress Has Not Vested the FDA with Exclusive Authority to Regulate Tortious Conduct That Constitutes "Fraud on the FDA."

Congress has rarely expressed an intent to preempt state tort remedies for defective or dangerous drugs, and when it does so, it expresses its intent clearly. Indeed, the House of Representatives has passed several bills that included a provision that, similar to state statutes, would preempt punitive

damages in state products liability cases involving "medical products" or "drugs or devices" where FDA approval was granted. *See, e.g.*, Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act of 2007, H.R. 2580, 110th Cong. (2007); Medical Malpractice Reform Act of 2006, H.R. 4838, 109th Cong. (2006); HEALTH Act of 2005, H.R. 5, 109th Cong. (2005); Common Sense Medical Malpractice Reform Act of 2003, H.R. 321, 108th Cong. (2003); Medical Malpractice Rx Act, H.R. 2103, 107th Cong. (2001).

Like Michigan's statute, however, these bills contained an exception permitting the recovery of punitive damages when the defendant,

> before or after premarket approval, clearance, or licensure of such medical product, knowingly misrepresented to or withheld from the [FDA] information that is required to be submitted under the [FDCA] that is material and is causally related to the harm which the claimant allegedly suffered; or * * * made an illegal payment to an official of the [FDA] for the purpose of either securing or maintaining approval, clearance, or licensure of such medical product.

H.R. 2580 § 7(c)(4); *see also* Mich. Comp. Laws § 600.2946(5)(a)–(b) (using substantially similar language). The bills do not stipulate that such proof of "fraud on the FDA" must be determined by the FDA itself, nor do they seek to preempt the traditional uses of tort law in this area. Rather, they permit a state tort plaintiff to prove "fraud on the FDA" in order to establish eligibility for punitive damages. Such bills therefore reflect the view that pursuing "fraud on the FDA" as part of a state tort lawsuit does not conflict with the FDA's ability to police

fraud. Evidence of fraud is simply relevant to both federal and state concerns. Indeed, if Congress intended to preempt state tort claims because "fraud on the FDA" was an exclusive federal issue, this proposed legislation would not be limited to the recovery of punitive damages.

Moreover, these bills follow an established pattern by Congress, recognized by the Court, not to use Congress's powers of preemption in such a way as to deprive injured parties of all remedies. *See Silkwood*, 464 U.S. at 251 ("It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."). On the rare occasion Congress has preempted state tort recovery in the area of dangerous drugs, it has expressly provided an alternative mechanism to compensate victims. *See* 42 U.S.C. § 300aa-10–34 (2000) (creating the National Vaccine Injury Compensation Program, preempting tort liability for vaccine manufacturers while also providing a separate method for obtaining compensation for a vaccine-related injury or death).

Congress's actions indicate that it would not erase the long history of state products liability actions and deprive tort victims of traditional remedies without clearly expressing its intent to do so. *See Bates*, 544 U.S. at 449–50 ("The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." (citing *Silkwood*, 464 U.S. at 251)). Given this history, it is implausible to think that Congress would by implication eliminate all forms of compensation for victims of the most egregious tortfeasors—

those who intentionally withhold information about a drug's toxicity in order to obtain FDA approval.

B. Because the FDA Does Not Consider Abstract Allegations of Fraud and the FDCA Contains No Remedies for Fraud Victims, Preemption Would Create an Extremely Harmful Regulatory Void.

While the FDA possesses various mechanisms to police fraudulent conduct, U.S. Br. 15-16, it apparently does not use them to protect victims of fraud and did not do so here. *See id.* at 21, 24. Moreover, the FDA's position is that there is "no private right of action to enforce the FDCA." *Id.* at 4. Yet respondents' allegations against petitioners, if proven,[10] will establish egregious and fraudulent misconduct that may be tantamount to criminal acts. *See, e.g.*, Resp. Br. 4-5 ("While aware as early as 1993 of Rezulin's potential harm to the liver, Warner-Lambert chose to omit from its FDA submissions information that showed this concern to be valid." (citing David Willman, *Risk Was Known As FDA OKd Fatal Drug*, L.A. Times, Mar. 11, 2001)). What ensued thereafter powerfully demonstrates why Congress did not intend the FDA to have the exclusive power to determine the remedies for persons injured or killed by Rezulin.

Respondents' allegations highlight the FDA's slow response to revelations of Rezulin's toxicity. Despite numerous "reports of serious adverse events [which] started to flow in to the FDA," only months

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[10] As respondents note, the early dismissal of their actions under F.R.C.P. 12(c) left them no opportunity to prove the facts on which they base their claims. Resp. Br. 5 n.1. The factual statement in their brief "reflect[s] what respondents will attempt to prove if the case proceeds." *Id.*

after approval, the agency did not withdraw its approval of the drug. *Id.* at 6. Rezulin was pulled off the market in Britain on December 1, 1997, "because 'the pace of liver injuries and deaths was by that point "unacceptably high."'" *Id.* at 7 (citing JA 34-35). In this country, by contrast, Rezulin was sold until March 2000, when "Warner-Lambert voluntarily withdrew [the drug] from the United States market." Pet. Br. 14. The FDA did not rescind its approval of Rezulin until 2003. 68 Fed. Reg. 1469 (2003).

Between 1997 and 2000, "[r]ather than withdrawing approval, the FDA negotiated a series of labeling changes with Warner-Lambert." Resp. Br. 6. During the three years petitioners marketed Rezulin, they realized approximately $1.8 billion in revenue. JA 28. Yet if petitioners prevail in this Court, they will never have to answer to a single Michigan claim that they wrongfully withheld evidence that Rezulin was too dangerous to be used by diabetics, or that they were engaged in the intentional tort of knowingly selling a toxic drug.

Despite the FDA's "core public health mission," the United States appears to acknowledge that victims of fraud are not a high priority for the FDA. *See* U.S. Br. 24. For example, the agency "does not have a process for considering allegations or making explicit findings of fraud in the abstract. Citizen petitions must seek specific types of administrative action, such as withdrawal of a drug's approval, not merely a finding of fraud." *Id.* (citation omitted). Moreover, "[w]hen FDA suspects fraud, it often reaches a settlement with the applicant in which the applicant pays a fine or takes corrective action (such as changes in labeling) without admitting liability." *Id.* at 24.

The United States thus indicates that the FDA's regulatory and enforcement mechanisms for addressing victims of fraud are not central to the agency's perception of its "core public health mission." *Id.* But given the congruence of the FDA's public health mission and the historic responsibility of the States to protect public health, *see, e.g., Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 203 (1824); *Oneida-Herkimer*, 127 S.Ct. at 1795, it is inconceivable that Congress intended the FDCA to leave plaintiffs such as respondents without any state remedy simply because proof of petitioners' negligence also establishes a regulatory violation. This is particularly true since the FDA, by its own admission, either ignored or, at best, used the fraud alleged by respondents as a bargaining chip to have Warner-Lambert voluntarily withdraw Rezulin from the market. *See* Resp. Br. 6-7; U.S. Br. 21. Congress would not have intended to preempt state law to leave such a regulatory void in which tort victims could not avail themselves of either federal or state protection.

Members of Congress know that "FDA officials in Washington repeatedly reject[] the recommendations of career field officials urging enforcement actions, even in cases involving death and serious injury." Minority Staff of H. Comm. on Government Reform, *Report on Prescription for Harm: The Decline in FDA Enforcement Action* 6 (June 2006), *available at* http://oversight.house.gov/documents/20060627101434-98349.pdf. Congress is also well aware that state-law tort remedies, not FDA regulation, are the central component of the nation's remedial scheme for persons injured or killed by defective products.

Consequently, and as this Court reasoned in *Pacific Gas & Elec. Co. v. State Energy Res. Conser. & Dev. Comm'n*, 461 U.S. 190, 207–08 (1983), "[i]t is

almost inconceivable that Congress would have left a regulatory vacuum" that the FDA candidly admits exists because it is not required to consider the interests of fraud victims. The "only reasonable inference is that Congress intended the States to continue to make these judgments." *Id.* at 208. The FDA can bargain away its limited interest in pursuing drug company fraud, but it has no authority to bargain away the state-law products liability claims of the victims of that fraud.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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